UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: 30-OCT-2007

Subject: **Difenoconazole.** Chronic and Acute Aggregate Dietary Exposure and Risk Assessments for the Section 3 Registration Request for Fruiting Vegetables, Pome Fruits, Sugar Beets, Tuberous and Corm Vegetables, and Imported Papaya.

PC Code: 128847 Decision#: 371264.
DP#: 341303 PP#s: 6F7115

Reviewer: Mohsen Sahafeyan, Chemist
Registration Action Branch 1/Health Effects Division (RAB1/HED; 7509P)

Through: William Cutchin, Chemist
Toiya Goodlow, Chemist
Dietary Exposure Science Advisory Council (DESAC)

And

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RAB1/HED (7509P)

To: Mohsen Sahafeyan, Risk Assessor
RAB1/HED (7509P)

Executive Summary

Aggregate (food + water) acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID™, ver. 2.03) model. This model uses food consumption data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII; 1994-1996 and 1998). The analyses were performed to support a Section 3 request for new uses of the fungicide difenoconazole [1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole] in/on fruiting vegetables, pome fruit, sugar beets, tuberous and corm vegetables, and imported papaya.

The Tier 1 acute and chronic analyses assumed tolerance-level residues, 100% crop treated (CT), and empirical and DEEM™ (ver. 7.76) default processing factors for most commodities. The resulting acute food exposure estimates were less than HED's level of concern (<100% of the acute population-adjusted dose (aPAD)) at the 95th percentile of the exposure distribution for U.S. general population (2% aPAD) and all population sub-groups; the most highly exposed population subgroup was all-infants <1 year old with 8% aPAD. The resulting chronic food exposure estimates were less than HED's level of concern (<100% of the chronic population-adjusted dose (cPAD)) for U.S. general population (18% cPAD) and all population sub-groups; the most highly exposed population subgroup was children 1-2 years old with 56% cPAD. A cancer dietary assessment was not conducted for difenoconazole because the cancer no-observable-adverse-effect- level (NOAEL) is higher than the chronic reference dose (RfD); therefore, the chronic dietary risk estimate is more protective.

The aggregate dietary (food + water) acute and chronic dietary exposure analyses for difenoconazole metabolite 1,2,4- triazole (1,2,4-T) from all registered and proposed triazole-based pesticide uses are conducted separately (Memo, M. Sahafeyan, DP#341803, 30-OCT-07) as an update to the previously conducted aggregate dietary exposure risk assessment for 1,2,4-T (Memo, M. Doherty, DP#322238, 1-NOV-2005). The updated 1,2,4-T dietary risk, adding the new use sites associated with the subject petition, showed only a very minimal increase from the previous risk estimates and therefore still is not of concern.

The aggregate dietary (food + water) acute and chronic dietary exposure analyses were also conducted separately for difenoconazole metabolites triazole alanine (TA) and triazole acetic acid (TAA) from all registered and proposed triazole-based pesticide uses (Memo, M. Sahafeyan, DP#344298, 30-OCT-07) as an update to the previously conducted aggregate dietary exposure risk assessment for TA + TAA (Memo, M. Doherty, DP#322239, 20-DEC-2005). The updated TA+TAA dietary risk, adding the new use sites associated with the subject petition, showed only a very minimal increase from the previous risk estimates and therefore still is not of concern.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the PAD. The PAD is equivalent to the point of departure (POD, NOAEL, LOAEL, e.g.) divided by the required uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million. References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 21-JUN-2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf ; or see SOP 99.6 (20-AUG-1999).

The most recent dietary risk assessment for difenoconazole was conducted by S. Levy (03-AUG-

2005; DP#319943).

II. Residue Information

Difenoconazole tolerances are published in 40 CFR§180.475.

Residues of Concern in Plants and Livestock: The HED Metabolism Assessment Review Committee (MARC) has determined that for tolerance expression and risk assessment purposes, the residue of concern is difenoconazole *per se* for plant and livestock commodities. The MARC, however, stated that if tolerances are proposed for difenoconazole resulting from foliar uses which result in higher residue levels of CGA-205375 than parent, then the need to include CGA-205375 should be reconsidered (Memo, G. Kramer, 22-JUL-1994; No DP#). Because the petitioner has now proposed foliar uses of difenoconazole, which result in higher residues in crop commodities, the need to include metabolite CGA 205375 in the tolerance expression and/or risk assessment has been re-examined. Based upon a review of the previously-submitted metabolism data for difenoconazole, HED concludes the residue of concern for both tolerance setting and risk assessment for the crops included in this petition is difenoconazole *per se*. However, HED concludes the residue of concern in livestock for tolerance setting and risk assessment are difenoconazole and its metabolite CGA 205375 (for more details, see the summary document, DP# 340379). Table 1 below summarizes tolerance expression and the residues of concern in plants and livestock commodities.

Table 1. *Difenoconazole* Residues of Concern in Plants and Ruminants.

Matrix	Residues of Concern	
	For Risk Assessment	**For Tolerance Expression**
Plants	Parent Only	Parent Only
Livestock Commodities	Parent and CGA 205375	Parent and CGA 205375
Milk	Parent and CGA 205375	Parent and CGA 205375
Water	Parent Only	NA

Recommended Tolerances: Based on the residue chemistry data submitted with the current petitions, HED recommended for establishment of the new food tolerances and revised tolerances on some ruminant commodities (DP# 340379, W. Wassell, 13-JULY-2005). The recommended, established, and revised tolerances are listed in Table 2 below.

Table 2. Tolerance Summary for Difenoconazole.

Commodity	Registered Tolerance (ppm)	Recommended Tolerance (ppm)
Fruit, Pome[1], (Group 11)	0.1	1.0

Table 2. Tolerance Summary for Difenoconazole.		
Commodity	Registered Tolerance (ppm)	Recommended Tolerance (ppm)
Vegetable, Fruiting, Group 8	none	0.60
Vegetable, Tuberous and Corm, subgroup 1C	none	0.01
Beet, sugar	none	0.30
Beet, sugar, tops	none	Remove
Papaya[1]	none	0.30
Apple, wet pomace	none	4.5
Beet, sugar, dried pulp	none	1.9
Potato, processed waste	none	0.04
Banana[1]	0.2	--------
Barley, grain	0.1	--------
Barley, hay	0.05	--------
Barley, straw	0.05	--------
Canola, seed	0.01	--------
Cattle fat[2]	0.05	0.10
Cattle, meat	0.05	--------
Cattle, meat byproducts[2]	0.05	0.10 (except for liver)
Cattle, liver	0.05	0.20
Corn, sweet, forage	0.01	--------
Corn, sweet, kernel plus cob with husks removed	0.01	--------
Corn, sweet, stover	0.01	--------
Cotton, gin byproducts	0.05	--------
Cotton, undelinted seed	0.05	--------
Egg[2]	0.05	0.10
Goat, fat[2]	0.05	0.10
Goat, meat	0.05	--------
Goat, meat byproducts[2]	0.05	0.10 (except for liver)
Goat, liver	0.05	0.20
Grape[1]	0.1	--------
Hog, fat[2]	0.05	0.10
Hog, meat	0.05	--------
Hog, meat byproducts[2]	0.05	0.10 (except for liver)
Horse, fat[2]	0.05	0.10
Horse, meat	0.05	--------
Horse, meat byproducts[2]	0.05	0.10 (except for liver)
Horse, liver	0.05	0.20
Milk	0.01	--------

Table 2. Tolerance Summary for Difenoconazole.		
Commodity	Registered Tolerance (ppm)	Recommended Tolerance (ppm)
Poultry, fat[2]	0.05	Remove
Poultry, meat[2]	0.05	Remove
Poultry, meat byproducts[2]	0.05	Remove
Rye, grain[1]	0.1	--------
Sheep, fat[2]	0.05	0.10
Sheep, meat	0.05	--------
Sheep, meat byproducts[2]	0.05	0.10 (except for liver)
Sheep, liver	0.05	0.20
Wheat, forage	0.1	--------
Wheat, grain	0.1	--------
Wheat, straw	0.1	--------

[1] Import tolerance.

[2] Due to the change in tolerance expression to include metabolite CGA 205375 in addition to the parent (difenoconazole) for ruminant commodities and egg, HED recommended new tolerances for ruminants fat (0.1 ppm), meat byproduct (except liver) (0.1 ppm), liver (0.2 ppm), and egg (0.1 ppm). In addition, based on the new feeding study, HED recommended removal of tolerances for poultry commodities (except egg).

As explained above, with the request for foliar use, the tolerance expression and the residues of concern are now changed to include CGA 205375 for livestock commodities. HED concluded that the established tolerances for milk (0.01 ppm) and meat of ruminants (0.05 ppm) are adequate to support the proposed uses; however, the tolerance levels for residues in meat byproducts (except liver), fat, and liver of cattle, goat, horse and sheep should be increased to 0.10, 0.10, and 0.2 ppm respectively (from the current level of 0.05 ppm). In addition, based on the new feeding study, HED recommended that the tolerances for poultry commodities (except egg) be removed and the egg tolerance be increased to 0.1 ppm.

Food Residues and processing factors used in the Acute and Chronic Analysis: The acute and chronic analyses assumed tolerance-level residues and 100% CT for all the registered and proposed crops. Tolerance-level residues were also assumed for all livestock tissues in this assessment. Experimental processing factors were used for apple juice (0.04x), potato chips (0.5x), potato granules/flakes (0.5x), sugar beet molasses (0.6x), sugar beet refined sugar (0.6x), tomato paste (1.6x), and tomato puree (0.5x); DEEM™ (ver. 7.76) default processing factors were assumed for other processed commodities.

III. Drinking Water Data

The drinking water values used in the dietary risk assessment were provided by the Environmental Fate and Effects Division (EFED; Memo, I. Maher, 19-JUN-2007; DP# 333319). EFED conducted a Tier II drinking water assessment from surface water sources using Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) model for the registered and proposed new uses and found that the highest estimated drinking water concentrations (EDWCs) are likely to be from surface water sources derived from aerial applications of difenoconazole to California ornamental nurseries at the maximum annual application rate of 0.53 lb ai/A. The

estimated drinking water residues for 1-in-10 year annual peak, 1-in-10 year annual mean, and 36-year annual mean are 13.3, 9.43, and 7.18 µg/L (ppb) respectively. The second highest EDWC was from Maine potatoes.

For ground water, SCI-GROW model indicates that difenoconazole concentrations are not likely to exceed 0.00128 µg/L (ppb) from either agricultural or non-agricultural uses.

In this assessment, 1-in-10-year annual peak (13.3 ppb), and 1-in-10-year annual mean (9.43 ppb) residue values were used for acute and chronic dietary exposure assessments respectively.

IV. DEEM-FCID™ Program and Consumption Information

Difenoconazole acute and chronic dietary exposure assessments were conducted using the DEEM-FCID™ (ver. 2.03), which incorporates consumption data from USDA's CSFII (1994-1996 and 1998). The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (*i.e.*, apple pie) are linked to EPA-defined food commodities (*i.e.*, apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (*i.e.*, orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (*i.e.*, those who reported eating relevant commodities/food forms) and a per-capita (*i.e.*, those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for Tiers 1 and 2, significant differences in user vs. per capita exposure and risk are identified and noted in the risk assessment.

V. Toxicological Information

On 08-SEP-1998, HED's Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology data base of difenoconazole and re-assessed the RfD established in 1994, as well as the toxicological endpoints for the dietary and occupational exposure risk assessments that were selected in 1994. At this meeting, the HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to difenoconazole as required by the Food Quality Protection Act (FQPA) of 1996 (HED Doc. No. 012873, 25-SEP-1998). In July, 2007, the RAB1 toxicologists and risk assessment team met to reevaluate the endpoints selected by the HIARC since new studies were submitted. RAB1 toxicologists and risk assessment team also reevaluated FQPA assessments. The risk assessment team concluded that the default 10x FQPA Safety Factor (SF) be reduced to 1x when assessing acute and chronic dietary exposures (Sahafeyan, M., DP#333320, 09-AUG-07). The relevant endpoints are shown in Table 3.

For purposes of this action, HED recently reviewed HED's 27-JUL-1994 Cancer Peer Review Committee (CPRC) report (Memo, Jess Rowland and Esther Rinde) on difenoconazole and the supporting data-evaluation records (DERs). HED concluded that difenoconazole is a very weak carcinogen, showing effects only at excessive doses. In retrospect, the CPRC should have classified this pesticide as a category C with no linear quantification of cancer risk. The cRfD, based on borderline liver effects in male rats at 24.1 mg/kg and a NOAEL of 0.96 mg/kg, would be protective of any carcinogenic effects seen in the mouse (Memo, S. Levy *et al.*, 05-AUG-2005; DP# 319944). Therefore, a cancer dietary assessment was *not* conducted for difenoconazole.

Table 3. Summary of Toxicological Doses and Endpoints for Difenoconazole for Use in Dietary Risk Assessments.

Exposure Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Relevant *Toxicological Effects*
Acute Dietary (All populations)	NOAEL = 25 mg/kg	UF_A = 10X UF_H = 10X UF_{FQPA} = 1X	aRfD = aPAD = 0.25 mg/kg/day	**Acute Neurotoxicity Study in Rats** LOAEL= 200 mg/kg in males based on reduced fore-limb grip strength in males on day 1.
Chronic Dietary (All populations)	NOAEL = 0.96 mg/kg/day	UF_A = 10X UF_H = 10X UF_{FQPA} = 1X	cRfD = cPAD = 0.01mg/kg/day	**Combined chronic toxicity/carcinogenicity (rat; dietary)** LOAEL = 24.1/32.8 mg/kg/day (M/F) based on cumulative decreases in body-weight gains.
Cancer (oral, dermal, inhalation)	Difenoconazole is classified as a Group C, possible human carcinogen with a non-linear (MOE) approach for human risk characterization (CPRC Document, 7/27/94, Memo, P. V. Shah dated March 3, 2007, HED Doc. No. 0054532)			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. *NOAEL = no observed adverse effect level.* LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a

critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

VI. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the aPAD or cPAD, respectively. The following paragraphs are summaries of the DEEM-FCID™ (ver. 2.03) acute and chronic exposure analyses.

Acute and chronic aggregate (food + water) analyses were performed using DEEM-FCID™ estimating the dietary exposure of the U.S. population and various population subgroups. The results are summarized in Tables 4 and 5 below for acute and chronic analyses respectively.

The resulting acute food exposure estimates were less than HED's level of concern (<100% aPAD) at the 95th percentile of the exposure distribution for US general population (2% aPAD) and all population sub-groups; the most highly exposed population subgroup was all-infants sub-population with 8% aPAD. The resulting chronic food exposure estimates were less than HED's level of concern (<100% cPAD) for U.S. general population (18% cPAD) and all population sub-groups; the most highly exposed population subgroup was children 1-2 years old with 56% cPAD. A cancer dietary assessment was not conducted for difenoconazole because the cancer NOAEL is higher than the chronic RfD; therefore, the chronic dietary risk estimate is more protective.

Table 4. Summary of acute Dietary Exposure and Risk for Difenoconazole at the 95th Percentile.

Population Subgroup	aPAD (mg/kg/day)	Exposure (mg/kg/day)	%cPAD
General U.S. Population	0.25	0.005772	2
All Infants (< 1 year old)		**0.020281**	**8**
Children 1-2 years old		0.016442	7
Children 3-5 years old		0.013839	6
Children 6-12 years old		0.008167	3
Youth 13-19 years old		0.003944	2
Females 13-49 years old		0.003842	2
Adults 20-49 years old		0.004267	2
Adults 50+ years old		0.003882	2

Table 5. Summary of Chronic Dietary Exposure and Risk for Difenoconazole.

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	%cPAD
General U.S. Population	0.01	0.001828	18
All Infants (< 1 year old)		0.005058	51
Children 1-2 years old		**0.005579**	**56**
Children 3-5 years old		0.004575	46
Children 6-12 years old		0.002670	27

Table 5. Summary of Chronic Dietary Exposure and Risk for *Difenoconazole*.			
Population Subgroup	**cPAD (mg/kg/day)**	**Exposure (mg/kg/day)**	**%cPAD**
Youth 13-19 years old		0.001307	13
Females 13-49 years old		0.001292	13
Adults 20-49 years old		0.001320	13
Adults 50+ years old		0.001433	14

The bolded %cPAD is the highest.

VII. Characterization of Inputs/Outputs

The acute and chronic analyses assumed tolerance-level residues, 100% CT, and empirical and DEEM™ default processing factors. Therefore, these analyses were considered conservative and could be further refined through the use of ARs for all commodities, % market share data for the proposed commodities, %CT data for registered commodities, and/or empirical processing factors for all commodities.

VIII. Conclusions

Acute and chronic aggregate (food + water) dietary risk assessments were conducted for difenoconazole using the DEEM-FCID™ (ver. 2.03) model and assumed tolerance-level residues, 100% CT, and empirical and DEEM™ default processing factors. The resulting acute and chronic aggregate exposure estimates were less than HED's level of concern. The most highly-exposed population subgroups in the acute (at the 95th percentile of the exposure distribution) and chronic analyses were all-infants <1 year old (8% aPAD) and children 1-2 years old (56% cPAD) respectively.

IX. Attachments

Attachment 1: DEEM-FCID™ Acute Residue File
Attachment 2: DEEM-FCID™ Acute Exposure Estimates
Attachment 3: DEEM-FCID™ Chronic Residue File
Attachment 4: DEEM-FCID™ Chronic Exposure Estimates

cc with all attachments: M. Sahafeyan (RAB1)
RDI: DESAC (10-JUL-2007)
Petition Number(s): PP#6F7115
DP#: 341303
PC Code: 128847
M. Sahafeyan:S10944:PY1:(703)-305-0776

Attachment 1: DEEM-FCID™ Acute Residue File

Filename: C:\Documents and Settings\msahafey\Desktop\difenconazole\difenoconazole_acute-080207.R98
Chemical: Difenoconazole
RfD(Chronic): .01 mg/kg bw/day NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): .25 mg/kg bw/day NOEL(Acute): 0 mg/kg bw/day
Date created/last modified: 08-02-2007/11:39:22/8 Program ver. 2.03

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	#2
11000070	11	Apple, fruit with peel	1.000000	1.000	1.000
11000080	11	Apple, peeled fruit	1.000000	1.000	1.000
11000081	11	Apple, peeled fruit-babyfood	1.000000	1.000	1.000
11000090	11	Apple, dried	1.000000	8.000	1.000
11000091	11	Apple, dried-babyfood	1.000000	8.000	1.000
11000100	11	Apple, juice	1.000000	0.040	1.000
11000101	11	Apple, juice-babyfood	1.000000	0.040	1.000
11000110	11	Apple, sauce	1.000000	1.000	1.000
11000111	11	Apple, sauce-babyfood	1.000000	1.000	1.000
95000230	O	Banana	0.200000	1.000	1.000
95000231	O	Banana-babyfood	0.200000	1.000	1.000
95000240	O	Banana, dried	0.200000	3.900	1.000
95000241	O	Banana, dried-babyfood	0.200000	3.900	1.000
15000250	15	Barley, pearled barley	0.100000	1.000	1.000
15000251	15	Barley, pearled barley-babyfood	0.100000	1.000	1.000
15000260	15	Barley, flour	0.100000	1.000	1.000
15000261	15	Barley, flour-babyfood	0.100000	1.000	1.000
15000270	15	Barley, bran	0.100000	1.000	1.000
21000440	M	Beef, meat	0.050000	1.000	1.000
21000441	M	Beef, meat-babyfood	0.050000	1.000	1.000
21000450	M	Beef, meat, dried	0.050000	1.920	1.000
21000460	M	Beef, meat byproducts	0.100000	1.000	1.000
21000461	M	Beef, meat byproducts-babyfood	0.100000	1.000	1.000
21000470	M	Beef, fat	0.100000	1.000	1.000
21000471	M	Beef,fat-babyfood	0.100000	1.000	1.000
21000480	M	Beef, kidney	0.100000	1.000	1.000
21000490	M	Beef, liver	0.200000	1.000	1.000
21000491	M	Beef, liver-babyfood	0.200000	1.000	1.000
01010520	1A	Beet, sugar	0.300000	1.000	1.000
01010521	1A	Beet, sugar-babyfood	0.300000	1.000	1.000
01010530	1A	Beet, sugar, molasses	0.300000	0.600	1.000
01010531	1A	Beet, sugar, molasses-babyfood	0.300000	0.600	1.000
15001260	15	Corn, pop	0.010000	1.000	1.000
15001270	15	Corn, sweet	0.010000	1.000	1.000
15001271	15	Corn, sweet-babyfood	0.010000	1.000	1.000
95001280	O	Cottonseed, oil	0.050000	1.000	1.000
95001281	O	Cottonseed, oil-babyfood	0.050000	1.000	1.000
11001290	11	Crabapple	1.000000	1.000	1.000
70001450	P	Egg, whole	0.100000	1.000	1.000
70001451	P	Egg, whole-babyfood	0.100000	1.000	1.000
70001460	P	Egg, white	0.100000	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.100000	1.000	1.000
70001470	P	Egg, yolk	0.100000	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.100000	1.000	1.000
23001690	M	Goat, meat	0.050000	1.000	1.000
23001700	M	Goat, meat byproducts	0.100000	1.000	1.000
23001710	M	Goat, fat	0.100000	1.000	1.000
23001720	M	Goat, kidney	0.100000	1.000	1.000
23001730	M	Goat, liver	0.200000	1.000	1.000

95001750	O	Grape	0.100000	1.000	1.000
95001760	O	Grape, juice	0.100000	1.200	1.000
95001761	O	Grape, juice-babyfood	0.100000	1.200	1.000
95001770	O	Grape, leaves	0.100000	1.000	1.000
95001780	O	Grape, raisin	0.100000	4.300	1.000
95001790	O	Grape, wine and sherry	0.100000	1.000	1.000
24001890	M	Horse, meat	0.050000	1.000	1.000
11002100	11	Loquat	1.000000	1.000	1.000
27002220	D	Milk, fat	0.010000	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.010000	1.000	1.000
27012230	D	Milk, nonfat solids	0.010000	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.010000	1.000	1.000
27022240	D	Milk, water	0.010000	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.010000	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.010000	1.000	1.000
08002340	8	Okra	0.600000	1.000	1.000
95002450	O	Papaya	0.300000	1.000	1.000
95002451	O	Papaya-babyfood	0.300000	1.000	1.000
95002460	O	Papaya, dried	0.300000	1.000	1.000
95002470	O	Papaya, juice	0.300000	1.000	1.000
11002660	11	Pear	1.000000	1.000	1.000
11002661	11	Pear-babyfood	1.000000	1.000	1.000
11002670	11	Pear, dried	1.000000	6.250	1.000
11002680	11	Pear, juice	1.000000	1.000	1.000
11002681	11	Pear, juice-babyfood	1.000000	1.000	1.000
08002700	8	Pepper, bell	0.600000	1.000	1.000
08002701	8	Pepper, bell-babyfood	0.600000	1.000	1.000
08002710	8	Pepper, bell, dried	0.600000	1.000	1.000
08002711	8	Pepper, bell, dried-babyfood	0.600000	1.000	1.000
08002720	8	Pepper, nonbell	0.600000	1.000	1.000
08002721	8	Pepper, nonbell-babyfood	0.600000	1.000	1.000
08002730	8	Pepper, nonbell, dried	0.600000	1.000	1.000
95002830	O	Plantain	0.200000	1.000	1.000
95002840	O	Plantain, dried	0.200000	3.900	1.000
25002900	M	Pork, meat	0.050000	1.000	1.000
25002901	M	Pork, meat-babyfood	0.050000	1.000	1.000
25002910	M	Pork, skin	0.100000	1.000	1.000
25002920	M	Pork, meat byproducts	0.100000	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.100000	1.000	1.000
25002930	M	Pork, fat	0.100000	1.000	1.000
25002931	M	Pork, fat-babyfood	0.100000	1.000	1.000
25002940	M	Pork, kidney	0.100000	1.000	1.000
25002950	M	Pork, liver	0.200000	1.000	1.000
01032960	1C	Potato, chips	0.010000	0.500	1.000
01032970	1C	Potato, dry (granules/ flakes)	0.010000	0.500	1.000
01032971	1C	Potato, dry (granules/ flakes)-b	0.010000	0.500	1.000
01032980	1C	Potato, flour	0.010000	1.000	1.000
01032981	1C	Potato, flour-babyfood	0.010000	1.000	1.000
01032990	1C	Potato, tuber, w/peel	0.010000	1.000	1.000
01032991	1C	Potato, tuber, w/peel-babyfood	0.010000	1.000	1.000
01033000	1C	Potato, tuber, w/o peel	0.010000	1.000	1.000
01033001	1C	Potato, tuber, w/o peel-babyfood	0.010000	1.000	1.000
11003100	11	Quince	1.000000	1.000	1.000
20003190	20	Rapeseed, oil	0.010000	1.000	1.000
20003191	20	Rapeseed, oil-babyfood	0.010000	1.000	1.000
15003280	15	Rye, grain	0.100000	1.000	1.000
15003290	15	Rye, flour	0.100000	1.000	1.000
26003390	M	Sheep, meat	0.050000	1.000	1.000
26003391	M	Sheep, meat-babyfood	0.050000	1.000	1.000
26003400	M	Sheep, meat byproducts	0.100000	1.000	1.000
26003410	M	Sheep, fat	0.100000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.100000	1.000	1.000

26003420	M	Sheep, kidney	0.100000	1.000	1.000
26003430	M	Sheep, liver	0.200000	1.000	1.000
08003740	8	Tomatillo	0.600000	1.000	1.000
08003750	8	Tomato	0.600000	1.000	1.000
08003751	8	Tomato-babyfood	0.600000	1.000	1.000
08003760	8	Tomato, paste	0.600000	1.600	1.000
08003761	8	Tomato, paste-babyfood	0.600000	1.600	1.000
08003770	8	Tomato, puree	0.600000	0.500	1.000
08003771	8	Tomato, puree-babyfood	0.600000	0.500	1.000
08003780	8	Tomato, dried	0.600000	14.300	1.000
08003781	8	Tomato, dried-babyfood	0.600000	14.300	1.000
08003790	8	Tomato, juice	0.600000	1.500	1.000
86010000	O	Water, direct, all sources	0.013300	1.000	1.000
86020000	O	Water, indirect, all sources	0.013300	1.000	1.000
15004010	15	Wheat, grain	0.100000	1.000	1.000
15004011	15	Wheat, grain-babyfood	0.100000	1.000	1.000
15004020	15	Wheat, flour	0.100000	1.000	1.000
15004021	15	Wheat, flour-babyfood	0.100000	1.000	1.000
15004030	15	Wheat, germ	0.100000	1.000	1.000
15004040	15	Wheat, bran	0.100000	1.000	1.000

Attachment 2: DEEM-FCID™ Acute Exposure Estimates

U.S. Environmental Protection Agency Ver. 2.02
DEEM-FCID ACUTE Analysis for *DIFENOCONAZOLE* (1994-98 data)
Residue file: difenoconazole_acute-080207.R98 Adjustment factor #2 NOT used.
Analysis Date: 08-02-2007/11:43:08 Residue file dated: 08-02-2007/11:39:22/8
Daily totals for food and foodform consumption used.
Run Comment: ""

Summary calculations (per capita):

Percentile	95th Percentile		99th Percentile		99.9th	
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
U.S. Population:	0.005772	2.31	0.012564	5.03	0.025721	10.29
All infants:	0.020281	8.11	0.033837	13.53	0.054454	21.78
Children 1-2 yrs:	0.016442	6.58	0.024990	10.00	0.055331	22.13
Children 3-5 yrs:	0.013839	5.54	0.021186	8.47	0.036055	14.42
Children 6-12 yrs:	0.008167	3.27	0.013544	5.42	0.027010	10.80
Youth 13-19 yrs:	0.003944	1.58	0.006254	2.50	0.011862	4.74
Adults 20-49 yrs:	0.003842	1.54	0.006155	2.46	0.010345	4.14
Adults 50+ yrs:	0.004267	1.71	0.006581	2.63	0.009989	4.00
Females 13-49 yrs:	0.003882	1.55	0.006511	2.60	0.011007	4.40

Attachment 3: DEEM-FCID™ Chronic Residue File

Filename: C:\Documents and Settings\msahafey\Desktop\difenconazole\difenoconazole_chronic-080207.R98
Chemical: Difenoconazole
RfD(Chronic): .01 mg/kg bw/day NOEL(Chronic): 4.7 mg/kg bw/day
RfD(Acute): .25 mg/kg bw/day NOEL(Acute): 25 mg/kg bw/day
Date created/last modified: 08-02-2007/11:40:44/8 Program ver. 2.03

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	#2
11000070	11	Apple, fruit with peel	1.000000	1.000	1.000
11000080	11	Apple, peeled fruit	1.000000	1.000	1.000
11000081	11	Apple, peeled fruit-babyfood	1.000000	1.000	1.000
11000090	11	Apple, dried	1.000000	8.000	1.000
11000091	11	Apple, dried-babyfood	1.000000	8.000	1.000
11000100	11	Apple, juice	1.000000	0.040	1.000
11000101	11	Apple, juice-babyfood	1.000000	0.040	1.000
11000110	11	Apple, sauce	1.000000	1.000	1.000
11000111	11	Apple, sauce-babyfood	1.000000	1.000	1.000
95000230	O	Banana	0.200000	1.000	1.000
95000231	O	Banana-babyfood	0.200000	1.000	1.000
95000240	O	Banana, dried	0.200000	3.900	1.000
95000241	O	Banana, dried-babyfood	0.200000	3.900	1.000
15000250	15	Barley, pearled barley	0.100000	1.000	1.000
15000251	15	Barley, pearled barley-babyfood	0.100000	1.000	1.000
15000260	15	Barley, flour	0.100000	1.000	1.000
15000261	15	Barley, flour-babyfood	0.100000	1.000	1.000
15000270	15	Barley, bran	0.100000	1.000	1.000
21000440	M	Beef, meat	0.050000	1.000	1.000
21000441	M	Beef, meat-babyfood	0.050000	1.000	1.000
21000450	M	Beef, meat, dried	0.050000	1.920	1.000
21000460	M	Beef, meat byproducts	0.100000	1.000	1.000
21000461	M	Beef, meat byproducts-babyfood	0.100000	1.000	1.000
21000470	M	Beef, fat	0.100000	1.000	1.000
21000471	M	Beef,fat-babyfood	0.100000	1.000	1.000
21000480	M	Beef, kidney	0.100000	1.000	1.000
21000490	M	Beef, liver	0.200000	1.000	1.000
21000491	M	Beef, liver-babyfood	0.200000	1.000	1.000
01010520	1A	Beet, sugar	0.300000	1.000	1.000
01010521	1A	Beet, sugar-babyfood	0.300000	1.000	1.000
01010530	1A	Beet, sugar, molasses	0.300000	0.600	1.000
01010531	1A	Beet, sugar, molasses-babyfood	0.300000	0.600	1.000
15001260	15	Corn, pop	0.010000	1.000	1.000
15001270	15	Corn, sweet	0.010000	1.000	1.000
15001271	15	Corn, sweet-babyfood	0.010000	1.000	1.000
95001280	O	Cottonseed, oil	0.050000	1.000	1.000
95001281	O	Cottonseed, oil-babyfood	0.050000	1.000	1.000
11001290	11	Crabapple	1.000000	1.000	1.000
70001450	P	Egg, whole	0.100000	1.000	1.000
70001451	P	Egg, whole-babyfood	0.100000	1.000	1.000
70001460	P	Egg, white	0.100000	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.100000	1.000	1.000
70001470	P	Egg, yolk	0.100000	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.100000	1.000	1.000
23001690	M	Goat, meat	0.050000	1.000	1.000
23001700	M	Goat, meat byproducts	0.100000	1.000	1.000
23001710	M	Goat, fat	0.100000	1.000	1.000
23001720	M	Goat, kidney	0.100000	1.000	1.000
23001730	M	Goat, liver	0.200000	1.000	1.000

95001750	O	Grape	0.100000	1.000	1.000
95001760	O	Grape, juice	0.100000	1.200	1.000
95001761	O	Grape, juice-babyfood	0.100000	1.200	1.000
95001770	O	Grape, leaves	0.100000	1.000	1.000
95001780	O	Grape, raisin	0.100000	4.300	1.000
95001790	O	Grape, wine and sherry	0.100000	1.000	1.000
24001890	M	Horse, meat	0.050000	1.000	1.000
11002100	11	Loquat	1.000000	1.000	1.000
27002220	D	Milk, fat	0.004000	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.004000	1.000	1.000
27012230	D	Milk, nonfat solids	0.004000	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.004000	1.000	1.000
27022240	D	Milk, water	0.004000	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.004000	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.004000	1.000	1.000
08002340	8	Okra	0.600000	1.000	1.000
95002450	O	Papaya	0.300000	1.000	1.000
95002451	O	Papaya-babyfood	0.300000	1.000	1.000
95002460	O	Papaya, dried	0.300000	1.000	1.000
95002470	O	Papaya, juice	0.300000	1.000	1.000
11002660	11	Pear	1.000000	1.000	1.000
11002661	11	Pear-babyfood	1.000000	1.000	1.000
11002670	11	Pear, dried	1.000000	6.250	1.000
11002680	11	Pear, juice	1.000000	1.000	1.000
11002681	11	Pear, juice-babyfood	1.000000	1.000	1.000
08002700	8	Pepper, bell	0.600000	1.000	1.000
08002701	8	Pepper, bell-babyfood	0.600000	1.000	1.000
08002710	8	Pepper, bell, dried	0.600000	1.000	1.000
08002711	8	Pepper, bell, dried-babyfood	0.600000	1.000	1.000
08002720	8	Pepper, nonbell	0.600000	1.000	1.000
08002721	8	Pepper, nonbell-babyfood	0.600000	1.000	1.000
08002730	8	Pepper, nonbell, dried	0.600000	1.000	1.000
95002830	O	Plantain	0.200000	1.000	1.000
95002840	O	Plantain, dried	0.200000	3.900	1.000
25002900	M	Pork, meat	0.050000	1.000	1.000
25002901	M	Pork, meat-babyfood	0.050000	1.000	1.000
25002910	M	Pork, skin	0.100000	1.000	1.000
25002920	M	Pork, meat byproducts	0.100000	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.100000	1.000	1.000
25002930	M	Pork, fat	0.100000	1.000	1.000
25002931	M	Pork, fat-babyfood	0.100000	1.000	1.000
25002940	M	Pork, kidney	0.100000	1.000	1.000
25002950	M	Pork, liver	0.200000	1.000	1.000
01032960	1C	Potato, chips	0.010000	0.500	1.000
01032970	1C	Potato, dry (granules/ flakes)	0.010000	0.500	1.000
01032971	1C	Potato, dry (granules/ flakes)-b	0.010000	0.500	1.000
01032980	1C	Potato, flour	0.010000	1.000	1.000
01032981	1C	Potato, flour-babyfood	0.010000	1.000	1.000
01032990	1C	Potato, tuber, w/peel	0.010000	1.000	1.000
01032991	1C	Potato, tuber, w/peel-babyfood	0.010000	1.000	1.000
01033000	1C	Potato, tuber, w/o peel	0.010000	1.000	1.000
01033001	1C	Potato, tuber, w/o peel-babyfood	0.010000	1.000	1.000
11003100	11	Quince	1.000000	1.000	1.000
20003190	20	Rapeseed, oil	0.010000	1.000	1.000
20003191	20	Rapeseed, oil-babyfood	0.010000	1.000	1.000
15003280	15	Rye, grain	0.100000	1.000	1.000
15003290	15	Rye, flour	0.100000	1.000	1.000
26003390	M	Sheep, meat	0.050000	1.000	1.000
26003391	M	Sheep, meat-babyfood	0.050000	1.000	1.000
26003400	M	Sheep, meat byproducts	0.100000	1.000	1.000
26003410	M	Sheep, fat	0.100000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.100000	1.000	1.000

26003420	M	Sheep, kidney	0.100000	1.000	1.000
26003430	M	Sheep, liver	0.200000	1.000	1.000
08003740	8	Tomatillo	0.600000	1.000	1.000
08003750	8	Tomato	0.600000	1.000	1.000
08003751	8	Tomato-babyfood	0.600000	1.000	1.000
08003760	8	Tomato, paste	0.600000	1.600	1.000
08003761	8	Tomato, paste-babyfood	0.600000	1.600	1.000
08003770	8	Tomato, puree	0.600000	0.500	1.000
08003771	8	Tomato, puree-babyfood	0.600000	0.500	1.000
08003780	8	Tomato, dried	0.600000	14.300	1.000
08003781	8	Tomato, dried-babyfood	0.600000	14.300	1.000
08003790	8	Tomato, juice	0.600000	1.500	1.000
86010000	O	Water, direct, all sources	0.009430	1.000	1.000
86020000	O	Water, indirect, all sources	0.009430	1.000	1.000
15004010	15	Wheat, grain	0.100000	1.000	1.000
15004011	15	Wheat, grain-babyfood	0.100000	1.000	1.000
15004020	15	Wheat, flour	0.100000	1.000	1.000
15004021	15	Wheat, flour-babyfood	0.100000	1.000	1.000
15004030	15	Wheat, germ	0.100000	1.000	1.000
15004040	15	Wheat, bran	0.100000	1.000	1.000

Attachment 4: DEEM-FCID™ Chronic Exposure Estimates

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for DIFENOCONAZOLE (1994-98 data)
Residue file name: C:\Documents and Settings\msahafey\Desktop\difenconazole\difenoconazole_chronic-080207.R98
Adjustment factor #2 NOT used.
Analysis Date 08-02-2007/11:48:36 Residue file dated: 08-02-2007/11:40:44/8
Reference dose (RfD, Chronic) = .01 mg/kg bw/day

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.001828	18.3%
U.S. Population (spring season)	0.001804	18.0%
U.S. Population (summer season)	0.001728	17.3%
U.S. Population (autumn season)	0.001941	19.4%
U.S. Population (winter season)	0.001836	18.4%
Northeast region	0.001877	18.8%
Midwest region	0.001871	18.7%
Southern region	0.001634	16.3%
Western region	0.002049	20.5%
Hispanics	0.002126	21.3%
Non-hispanic whites	0.001806	18.1%
Non-hispanic blacks	0.001626	16.3%
Non-hisp/non-white/non-black	0.002069	20.7%
All infants (< 1 year)	0.005058	50.6%
Nursing infants	0.003030	30.3%
Non-nursing infants	0.005828	58.3%
Children 1-6 yrs	0.004741	47.4%
Children 7-12 yrs	0.002510	25.1%
Females 13-19 (not preg or nursing)	0.001233	12.3%
Females 20+ (not preg or nursing)	0.001348	13.5%
Females 13-50 yrs	0.001444	14.4%
Females 13+ (preg/not nursing)	0.001768	17.7%
Females 13+ (nursing)	0.001691	16.9%
Males 13-19 yrs	0.001374	13.7%
Males 20+ yrs	0.001362	13.6%
Seniors 55+	0.001455	14.5%
Children 1-2 yrs	0.005579	55.8%
Children 3-5 yrs	0.004575	45.7%
Children 6-12 yrs	0.002670	26.7%
Youth 13-19 yrs	0.001307	13.1%
Adults 20-49 yrs	0.001320	13.2%
Adults 50+ yrs	0.001433	14.3%
Females 13-49 yrs	0.001292	12.9%

13544

R154254

Chemical:	**Difenoconazole**
	PC Code:
	128847
HED File Code:	**11000 Chemistry Reviews**
Memo Date:	**10/30/2007**
File ID:	**DPD341303**
	DPD341803
	DPD322238
	DPD344298
	DPD322239
	DPD340379
	DPD333319
	DPD333320
	DPD319944
Accession #:	**000-00-0122**

HED Records Reference Center
11/15/2007